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Chugai Files for Additional Indication of Alecensa for Postoperative Adjuvant Therapy for *ALK* Fusion Gene-Positive Non-Small Cell Lung Cancer

- The application was based on the ALINA study, the first phase III clinical study that demonstrated favorable efficacy of an anaplastic lymphoma kinase (ALK) inhibitor as an adjuvant therapy for ALK-positive non-small cell lung cancer (NSCLC)
- Application for orphan drug designation has been submitted, and if designated, approval review will be subject to priority review

TOKYO, December 15, 2023 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) today announced that it filed regulatory application with the Ministry of Health, Labour and Welfare (MHLW) for the additional indication of an ALK inhibitor Alecensa® Capsules 150 mg (Hereafter Alecensa) for Postoperative adjuvant therapy for *ALK* fusion gene-positive non-small cell lung cancer. An application for orphan drug designation has been submitted for this indication, and if designated, the review of approval for the additional indication will be subject to priority review.

“We are pleased to have filed for additional indication of Alecensa, a Chugai original product, in Japan for the adjuvant treatment of ALK-positive NSCLC,” said Chugai’s President and CEO, Dr. Osamu Okuda. “Alecensa is the first ALK inhibitor to demonstrate efficacy as an adjuvant therapy, with the potential to significantly change the patient journey in early-stage lung cancer. We remain committed to getting this drug approved for patients as quickly as possible.”

The application is based on results from the ALINA study, a global Phase 3 study of Alecensa as an adjuvant therapy in patients with completely resected ALK-positive NSCLC. The study results showed that Alecensa reduces the risk of disease recurrence or death by 76% (hazard ratio [HR]=0.24, 95% CI: 0.13-0.43, p<0.0001) compared with platinum-based chemotherapy in people with completely resected stage IB (tumour ≥4cm) to IIIA ALK-positive NSCLC.[1] The safety and tolerability of Alecensa in this trial were consistent with previous trials in the metastatic setting and no unexpected safety findings were observed.[1]

Chugai Pharmaceutical, a leading company in the oncology field, remains committed to addressing unmet medical need in cancer treatment with innovative medicines for patients and healthcare professionals.

About the ALINA study

The ALINA study [NCT03456076] is a Phase III, randomised, active-controlled, multicentre, open-label study evaluating the efficacy and safety of adjuvant Alecensa (alectinib) compared with platinum-based chemotherapy in people with completely resected stage IB (tumour ≥4cm) to IIIA (UICC/AJCC 7th edition) anaplastic lymphoma kinase (ALK)-positive NSCLC. The study includes 257 patients who were randomly assigned to either the investigational or control treatment arm. The primary endpoint is disease-

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free survival. Secondary outcome measures include overall survival and percentage of patients with adverse events.

About Alecensa

Alecensa is a highly selective, central nervous system-active, oral medicine created at Chugai, a member of the Roche Group, Kamakura Research Laboratories for people with non-small cell lung cancer (NSCLC) whose tumours are identified as anaplastic lymphoma kinase (ALK) positive. Alecensa is already approved in over 100 countries as an initial (first-line) and second-line treatment for ALK-positive, metastatic NSCLC, including in the United States, Europe, Japan and China. In Japan, Alecensa has also been approved for the treatment of recurrent or refractory *ALK* fusion gene-positive anaplastic large cell lymphoma.

About lung cancer

Lung cancer is one of the leading causes of cancer death globally.[2] Each year 1.8 million people die as a result of the disease; this translates into more than 4,900 deaths worldwide every day.[2] In Japan, 127 thousand people are affected by this disease (2019) .[3] Lung cancer can be broadly divided into two major types: non-small cell lung cancer (NSCLC) and small-cell lung cancer (SCLC). NSCLC is the most prevalent type, accounting for around 85% of all cases.[4] Today, about half of all people with early lung cancer (45-76%, depending on disease stage) still experience a cancer recurrence following surgery, despite adjuvant chemotherapy.[5] Treating lung cancer early, before it has spread, may help prevent the disease from returning and provide people with the best opportunity for a cure.[6]

Source:

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3. Cancer Statistics, Cancer Information Service, National Cancer Center, Japan (National Cancer Registry) [Internet; cited 2023 December] Available from: https://ganjoho.jp/reg_stat/statistics/stat/cancer/12_lung.html (Japanese Only)
4. American Cancer Society: What Is Lung Cancer? [Internet; cited 2023 December] Available from: https://www.cancer.org/cancer/types/lung-cancer/about/what-is.html
5. Pignon JP et al. Lung Adjuvant Cisplatin Evaluation: A Pooled Analysis by the LACE Collaborative Group. J Clin Oncol. 2008;26:3552-3559.
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